

LETTER

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December 13, 2005

Division of Dockets Management
Food and Drug Administration, Room 1061, (HFA-305)
5630 Fisher's Lane
Rockville, MD 20852

Docket Number 95S-0158 (BB IND #10,719)

RE: BB IND 10,719, POLY-SFH-P INJECTION [Polymerized Human Hemoglobin (Pyridoxylated), PolyHeme[®]], Protocol RTBSE-11-(N): Publicly Disclosed Information

Dear Sir:

Reference is made to our Investigational New Drug Application (IND) for Poly-SFH-P Injection for acute trauma, BB IND #10,719.

In conformance with 21 CFR 312.54(a) and the Draft Guidance for Industry entitled *Exception from Informed Consent Requirements for Emergency Research* (March 30, 2000) which require that Institutional Review Board (IRB) information concerning public disclosure be submitted to this Docket for clinical investigations involving an exception from informed consent [21 CFR 50.24(a)(7)(iii)], we provide documentation for the following sites in Detroit, Michigan:

Detroit Receiving Hospital

IRB: Human Investigation Committee
4201 St. Antoine Boulevard-UHC-6G
Detroit, MI 48201

Sinai-Grace Hospital

IRB: Human Investigation Committee
4201 St. Antoine Boulevard-UHC-6G
Detroit, MI 48201

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A copy of this submission is being submitted to BB IND #10,719.

If you have any comments or questions, please contact the undersigned at 847-864-3500.

Sincerely,

A handwritten signature in black ink, appearing to read "Eva Essig". The signature is written in a cursive style with a large initial "E".

Eva Essig, PhD
Vice President, Regulatory Affairs and Quality